Remarks

The Restriction Requirement

The Examiner divided the claims into six groups: group I, claims 1-5 and 11-18, drawn to a vaccine for Epstein-Barr viral autoimmune disorder comprising Epstein-Barr viral peptides; group II, claims 1-5 and 11-18, drawn to a vaccine for Epstein-Barr viral autoimmune disorder comprising Epstein-Barr viral nucleic acids; group III, claims 1-5 and 11-18, drawn to a vaccine for Epstein-Barr viral autoimmune disorder comprising Epstein-Barr viral carbohydrates; group IV, claims 6-10 and 19-22, drawn to a diagnostic assay for detecting antibodies to Epstein-Barr virus; group V, claims 23-25, drawn to an *in vivo* screen for therapeutic compounds; and group VI, claim 26, drawn to a screen for genetic markers. Groups I-III were additionally classified by the species of the various diseases listed in claim 15, and group IV was classified by the peptides with a sequence selected from one of Sequence ID Nos. 1-3, 7, or 13-38.

Applicants have elected to prosecute the claims drawn to a vaccine and method of vaccinating, i.e, the subject of groups I, II and III. It is submitted that the claims of Groups I, II, and III should properly be treated as genus/species claims wherein claims 3, 4, 13, and 14 recite specific specie. Should the claims be treated as such, the species of peptides is elected for prosecution at this time, with a further election of the peptide of claim 4 as the species within the elected species, and with the understanding that claims 1, 2, 5, 11, 12, and 15-18 are generic.

The Restriction Requirement Is Improper

MPEP §806.04(a) states that while the general rule is that restriction may be required to one of two or more independent inventions, 37 C.F.R. §1.141 makes an exception to this, providing that a reasonable number of species may be claimed in one application if the other conditions of the rule are met. The other conditions are that the application include an allowable claim generic to all of the species and that the claims to species in excess of one are written in dependent form or otherwise include all of the limitations of the generic claim. A reasonable number of species is typically considered to be five or less. MPEP 806.04(b) further states: "Where inventions as disclosed and claimed are both 1) species under a claimed genus and b) related, then the question of restriction must be determined by both the practice applicable to election of species and the practice applicable to other types of restrictions . . . . **If restriction is improper under either practice, it should not be required.**" In the case at hand restriction is improper under genus/species practice, at least.

The Claims Are Proper Genus/Species Claims

Claims 1 and 11 recite a vaccine for alleviating or preventing autoimmune disorders induced by infection with Epstein-Barr virus comprising Epstein-Barr virus or a component thereof. Claims 3, 4, 13, and 14 recite specific embodiments of the Epstein-Barr virus or its components that can be used. The specific embodiments recited in claims 3, 4, 13, and 14 are species of the generic invention. As defined in MPEP §806.04(d), a generic claim must read on or encompass all the disclosed species or embodiments of the invention. Moreover,

the generic claim should include no material element additional to those recited in the species claims. These conditions are met by the claims herein which are properly defined as genus/species.

The requirements of 37 C.F.R. §1.141 are met by the claims herein. A reasonable number of species, less than five, are recited. Generic claims 1 and 11 read on all of the species that are claimed. The claims directed to species, claims 3, 4, 13, and 14, are dependent on the generic claims 1 or 11.

The Markush Group of Claims 3 and 13 is Proper

Claims 3 and 13 are directed to a vaccine for alleviating or preventing autoimmune disorders induced by infection with Epstein-Barr virus that includes a component of Epstein-Barr virus "selected from the group consisting of peptides or proteins expressed from recombinant DNA or RNA with sequence identity to Epstein-Barr virus, viral DNA or RNA, and carbohydrate components of the Epstein-Barr virus." The Markush group is objected to as improper, for including "compounds that do not share a common core structure and function."

MPEP §2173.05(h) explains that "[t]he materials set forth in the Markush group ordinarily must belong to a recognized physical or chemical class or to an art-recognized class. However, when the Markush group occurs in a claim reciting a process or a combination (not a single compound), it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is mainly

responsible for their function in the claimed relationship and it is clear from their very nature or from the prior art that all of them possess this property."

The present claims are drawn to a vaccine which includes either the Epstein-Barr virus or a component thereof. Claims 3 and 13 specify that the component of the Epstein-Barr virus can be a peptide, viral DNA or RNA, or a carbohydrate, derived from the virus. These species have a property in common in that they can serve as antigens for anti-Epstein-Barr viral antibodies. It is clear from their nature, the prior art, and the application that embodiments of all three species possess this property.

Conclusion

The restriction requirement is improper and all of the claims in groups I-III should have been grouped together as drawn to a vaccine, with perhaps an election of species as to the peptide, nucleic acid or carbohydrates. Applicants elect to prosecute the species of peptides, with a further election of the peptide of claim 4 as the species within the elected species. Groups I-III should be examined together, since they are all drawn to a vaccine.